

Terrestrial Animal Health Standards Commission February 2016

CHAPTER 6.8.

MONITORING OF THE QUANTITIES AND USAGE PATTERNS OF ANTIMICROBIAL AGENTS IN FOOD-PRODUCING ANIMALS

Article 6.8.1.

Definition and purpose

For the purposes of this chapter, therapeutic use of antimicrobial agents means the administration of antimicrobial agents to animals for treating and controlling infectious diseases infections.

The purpose of these recommendations is to describe an approach to the monitoring of the quantities of antimicrobial agents used in food-producing animals.

In order to evaluate antimicrobial exposure in food-producing animals, quantitative information should be collected to monitor usage patterns by animal species, antimicrobial agents or class, type of use (therapeutic or non-therapeutic) and route of administration.

Article 6.8.2.

Objectives

The information provided in these recommendations is essential for antimicrobial resistance *risk analyses* and planning purposes and should be read in conjunction with Chapters 6.7. and 6.10. This information is necessary for interpreting antimicrobial resistance surveillance data and can assist in responding to problems of antimicrobial resistance in a precise and targeted way. The continued collection of this basic information will also help to give an indication of trends in the use of *antimicrobial agents* in *animals* over time and potential associations with antimicrobial resistance in *animals*. This information may also assist in *risk management* to evaluate the effectiveness of efforts to ensure responsible and prudent use and mitigation strategies (for example, by identifying changes in veterinary prescribing practices) and to indicate where change of antimicrobial usage practices might be appropriate. The publication of these data is important to ensure transparency and to allow all interested parties to assess trends, to perform *risk assessments* and for *risk communication* purposes.

Article 6.8.3.

Development and standardisation of antimicrobial monitoring systems

Systems to monitor antimicrobial usage consist of the following elements:

1. Sources of antimicrobial data

a) Basic sources

Sources of data will vary from country to country. Such sources may include customs, import and export data, manufacturing and sales data.

b) Direct sources

Data from *veterinary medicinal product* registration authorities, wholesalers, retailers, pharmacists, *veterinarians*, feed stores, feed mills and pharmaceutical industry associations can be efficient and practical sources. A possible mechanism for the collection of this information is to make the provision of appropriate information by pharmaceutical manufacturers to the regulatory authority one of the requirements of antimicrobial registration.

c) End-use sources (veterinarians and food animal producers)

This may be appropriate when basic or direct sources cannot be used for the routine collection of the information or when more accurate and locally specific information is required (such as off label use).

Periodic collection of this type of information may be sufficient.

Collection, storage and processing of data from end-use sources should be carefully designed, well managed and have the capability to produce accurate and targeted information.

d) Other sources

Non-conventional sources including Internet sales data related to *antimicrobial agents* could be collected where available.

Member Countries may wish to consider, for reasons of cost and administrative efficiency, collecting medical, food-producing animal, agricultural and other antimicrobial use data in a single programme. A consolidated programme would also facilitate comparisons of animal use with human use data for *risk analysis* purposes and help to promote optimal usage of *antimicrobial agents*.

2. Types and reporting formats of antimicrobial usage data

a) Type of antimicrobial use data

The data collected at minimum should be the weight in kilograms of the active ingredient of the antimicrobial(s) used in food-producing animals per year. It is possible to estimate total usage by collecting sales data, prescribing data, manufacturing data, import and export data or any combination of these.

The total number of food-producing animals by species, type of production and their weight in kilograms for food production per year (as relevant to the country of production) is essential basic information.

Information on dosage regimens (dose, dosing interval and duration of the treatment) and route of administration are elements to include when estimating antimicrobial usage in food-producing animals.

b) Reporting formats of antimicrobial use data

The *antimicrobial agents*, classes or sub-classes to be included in data reporting should be based on current known mechanisms of antimicrobial activity and antimicrobial resistance data.

Nomenclature of *antimicrobial agents* should comply with international standards where available.

For active ingredients present in the form of compounds or derivatives, the mass of active entity of the molecule should be recorded. For *antimicrobial agents* expressed in International Units, the factor used to convert these units to mass of active entity should be stated.

The reporting of antimicrobial use data may be further organised by species, by route of administration (specifically in-feed, in-water, injectable, oral, intramammary, intra-uterine and topical) and by type of use (therapeutic or non-therapeutic).

Regarding data coming from end-use sources, further breakdown of data for analysis of antimicrobial use at the regional, local, *herd* and individual *veterinarian* or veterinary practice levels may be possible.

Article 6.8.4.

Interpretation

According to the OIE *risk assessment* guidelines (refer to Chapter 6.10.), factors such as the number or percentage of *animals* treated, treatment regimes, type of use and route of administration are key elements to consider.

When comparing antimicrobial use data over time, changes in the size and composition of animal populations should also be taken into account.

The interpretation and communication of results should take into account factors such as seasonality and disease conditions, animal species and age affected, agricultural systems (e.g. extensive range conditions and feedlots), animal movements, and dosage regimens with *antimicrobial agents*.

— Text deleted.